Regulation of Wood Preservatives in Canada

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Introduction

The Canadian pesticide regulatory review process presently entails the application of standards which are frequently higher than:

a) standards used to assess parallel applications for the same or similar chemicals in other sectors;

b) are used in U.S. and most other developed countries.

This difference can be attributed to a regulatory climate in which the Canadian public demands the highest level of health and environmental protections. As a result, pesticide standards are being pushed up by a public demand for higher levels of health and environmental protection.

A Regulatory Management approach, involving consultation with stakeholders, is being used for pesticide registration decisions when there is absence of a complete science base and support of all federal pesticide regulatory departments.

Wood Preservatives in Canada

Officials of the Pesticide Directorate, under the authority of the Pest Control Products Act, ensure timely and acceptable regulatory decisions are made for pesticide products. Decisions are considered "acceptable' in the context of human health, environmental safety, and merit and value.

Wood Preservatives are regulated in Canada under the Pest Control Products Act and Regulations. As such, products undergo a pre-market assessment of the hazards and benefits associated with the proposed uses as described on the proposed product label.

Presently wood preservative products represent approximately four per cent of the active ingredients contained in registered pesticide products and are registered for use areas such as pressure treatment, sapstain control, millwork and remedial applications

Requests for registration of new products are subjected to a rigorous assessment of health effects (both acute and long term) as well as environmental impact. The number and nature of studies requested is largely dependent upon the manner of intended use.

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In order to provide some general assistance and guidance to manufacturers concerning data development, guideline documents exist describing what scientific studies may be requested by federal regulatory officials to support a product registration. For sapstain control products, a guideline is currently being developed to provide registrants specific assistance in identifying which studies will be requested.

Once scientific data are provided to federal regulatory officials, assessments are done by Environmental Canada on environmental fate (in the areas of environmental chemistry and environmental toxicology) and by Health and Welfare Canada on toxicology and occupational and bystander exposure (see Figure 1).

Since the Canadian public demands the highest level of health and environmental protection, there are times when a full compliment of data will be requested from product manufacturers. Frequently manufacturers will indicate that to invest in the development of more studies is not an economically viable option especially when requirements seem to move during the long periods of consideration, negotiation and testing. Hence, some applications are subsequently withdrawn. However, at times, there is information to suggest that the regulatory decision should be given broader consideration via the regulatory management approach (see Figure 2).

In the absence of a regulatory management approach, as was used for sapstain chemicals, the position of defending a "go", i.e. register decision without a) a complete science base; and b) support of the full regulatory team (i.e. Health and Welfare and Environment Canada) seemed untenable for <u>both</u> industry and Agriculture Canada.

The likelihood of federal regulators being called upon to defend a "go" decision is high, recognizing a) the increasing profile of the industrial sector and b) the spotlight will likely shift to non-traditional applications with the greater environmental awareness developing since the introduction to Canadian Environmental Protection Act (CEPA).

The Regulatory Management decision making process was applied specifically in the consideration of wood preservative products for sapstain control. Antisapstain products which were registered at he time were the subject of a special review as a part of the re-evaluation of pentachlorophenol and a resulting interest in alternate products. During that review process, the science bases supporting the existing registered products were the subject of close scrutiny. Proposals for alternative products were also suggested by B.C. Council of Forest

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Industries. The challenge that was experienced in applying the regulatory management decision process was to meld together two imprecise components and emerge with an acceptable decision. These two components are 1) a science component consisting of a hazard/value assessment - based on facts and assumptions plus 2) a public policy component which is a complex mixture of highly intangible but legitimate concerns.

The public policy component of this decision making process is, by nature, open and honest. It is publically accessible and is prepared to field questions, challenges and criticism. It is also inherently prepared to recognize the judgmental element in BOTH the risk/benefit assessments and the public policy component. It is important that the process of regulatory management recognize that the concern factors are very real, intrinsic parts of the whole picture.

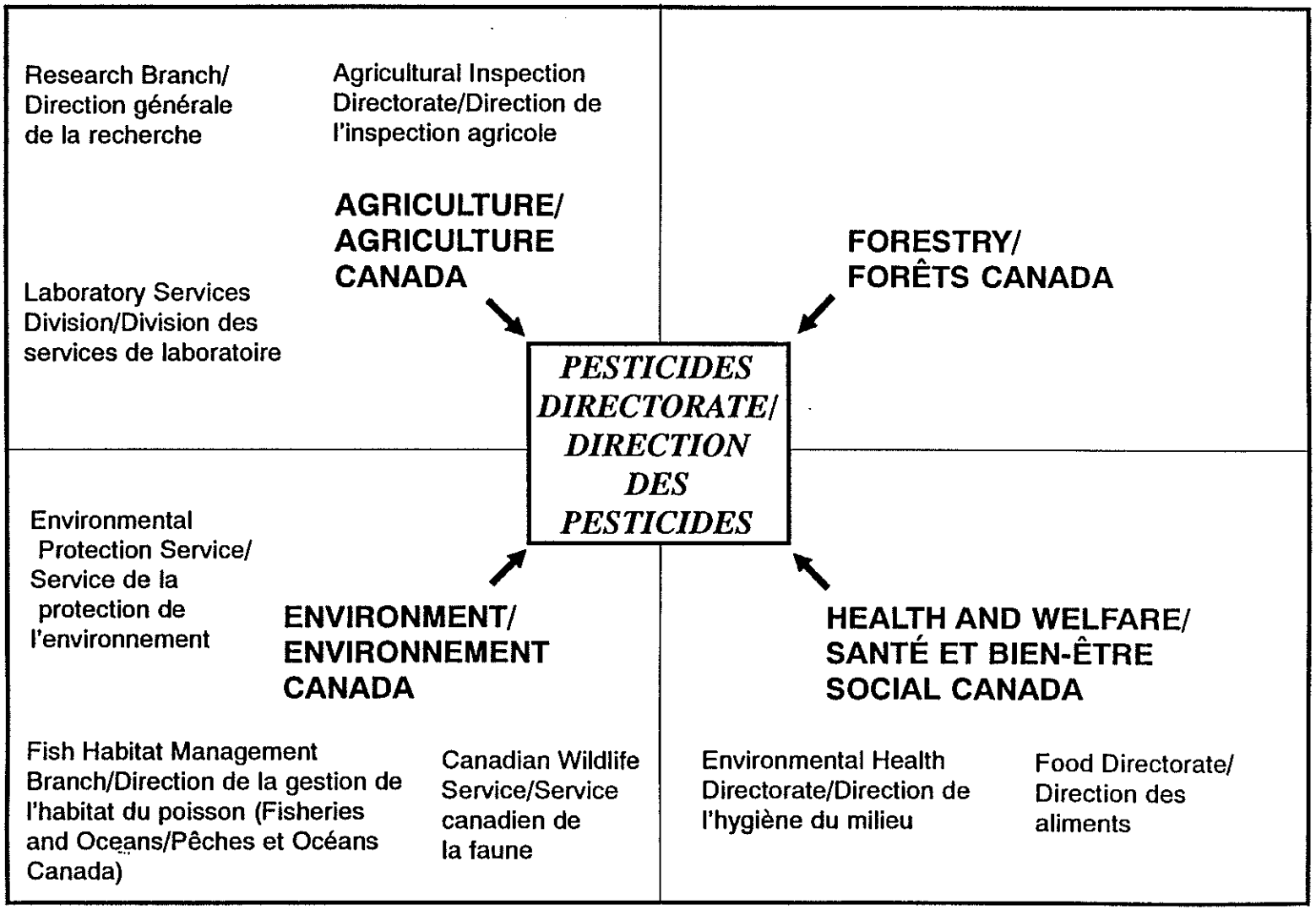
The resulting product from this decision process is a written comprehensive rationale for decisions.

Considerations for Future in the Wood Preservation Pesticides

As a continuation of the examination of products currently in use for wood preservation, an Announcement to Re-evaluate products used in heavy duty wood preservation will be released in 1992. Re-evaluating entails a reassessment of the heavy duty uses based on a review of the science base. Once a thorough review of the hazards associated with use (as per the existing science base) is completed, then regulatory decisions may emerge. It is possible that the regulatory management process will be used in order to formulate a viable registration decision.

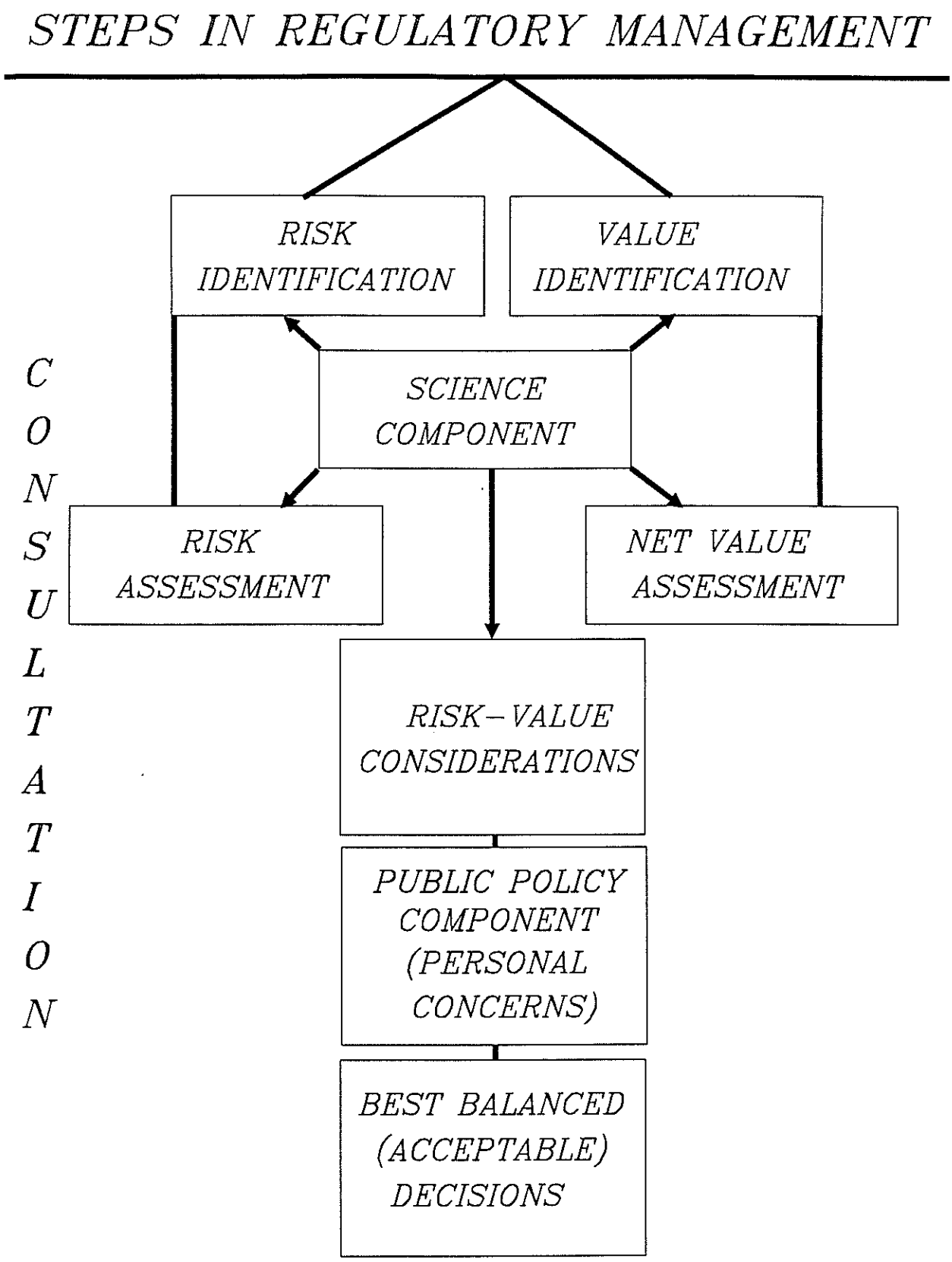
Several other agencies are also exploring health, safety and environmental fate questions due to use of Heavy Duty Wood Preservative products. Their investigations and findings may provide useful background and information that will ultimately contribute to a best balanced decision.

Figure 1



PESTICICES DIRECTORATE RELIES ON INPUT FROM A WIDE RANGE OF *FEDERAL ADVISORS TO* REACH BEST-BALANCED REGULATORY DECISIONS.

Figure 2


STEPS IN REGULATORY MANAGEMENT
RISK IDENTIFICATION
VALUE IDENTIFICATION
SCIENCE COMPONENT
RISK ASSESSMENT
NET VALUE ASSESSMENT
RISK–VALUE CONSIDERATIONS
PUBLIC POLICY COMPONENT (PERSONAL CONCERNS)
BEST BALANCED (ACCEPTABLE) DECISIONS
CONSULTATION
COMMUNICATION